GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:201
ANSWERED ON:15.12.2004
DRUG REGULATORY SYSTEM
Paswan Shri Sukdeo;Yadav Shri Ram Kripal

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has any plan to make stronger and stringent laws for Drug Regulatory System so as to make the implementing authority more effective for the protection of public health;

(b) if so, whether due to loopholes in inspection mechanism, quality of drugs and tracking of spurious or adulterated drugs are not properly monitored;

(c) if so, whether globally banned/withdrawn drugs are still allowed to be sold in India;

(d) if so, whether many drugs are being sold in the market without the mandatory approval of the authority;

(e) whether the Government is aware that cost of the medicines is down to roughly 1/10th of its production cost in West, but in India it is very much on the high side;

(f) if so, the details thereof; and

(g) the action taken/proposed to be taken by the Government to review the Drugs and Cosmetic Act, 1940?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(g): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 201 FOR 15TH DECEMBER, 2004

The provisions of Drugs & Cosmetics Act, 1940, and the Rules thereunder which regulate import, manufacture and sale of drugs and cosmetics have been amended from time to time to ensure safe, efficacious and quality drugs manufactured and sold in the Indian market. This is an on-going process.

Under the provisions of Drugs and Cosmetics Act, 1940, and Rules framed thereunder, the State Governments, through their respective Drugs Control Organizations, are empowered to regulate manufacture of drugs and to monitor the quality of drugs moving in the inter-state commerce. The Rules have been amended recently to prescribe more stringent requirements for Good Manufacturing Practices (GMPs) to be followed by all manufacturers in the country. Rules have also been amended to require all overseas manufacturers to obtain registration for drugs being imported into the country.

Based on the recommendations of the Mashelkar Committee, the Ministry of Health and Family Welfare, Government of India, had on December 22, 2003, introduced a Bill, called the Drugs & Cosmetics (Amendment Bill 2003) in the Lok Sabha to further amend the Drugs & Cosmetics Act, 1940. The objective of the Bill was to make the prescribed penalties and fines for offences related to manufacture and sale of spurious drugs more stringent. As the Bill lapsed due to the dissolution of the 13th Lok Sabha, a fresh amendment Bill is now proposed to be introduced for amendment of the said Act. The amended Act, when enacted, will provide for more stringent penalties; make offences relating to spurious drugs cognizable and non-bailable; provide for the trial of such cases by special courts; provide powers to police officers to investigate and launch prosecutions; and provide for compounding of offences.

Under the provisions of Drugs and Cosmetics Act, 1940, and Rules framed thereunder, the State Governments, through their respective Drugs Control Organizations, are empowered for licensing and inspection of manufacturing and sale establishments; ensuring quality of drugs as per prescribed norms; and tracking down and proceeding against the manufacture and/or sale of spurious or adulterated drugs.

However, it has been observed that there is lack of uniformity in respect of infrastructure and in the status of implementation of the provisions of the Drugs & Cosmetics Act and Rules thereunder amongst the States. The Drugs Control Administrations are advised from time to time to tighten the implementation of the provisions of the said Act and take effective steps for unearthing cases of spurious and adulterated drugs. In addition, a national project for building the capacity of and strengthening of State Drug administrations has been initiated in October, 2003 .

There is no system of global ban of drug formulations. Drugs banned, withdrawn or not permitted in one country may continue to be

used in other countries. Action for banning of a drug is taken by national governments after examining over all benefit-risk ratio, adverse events reported abroad or in the country, reports of technical committees, views of international expert organizations, usage and strength of the said drug permitted and its requirement in the country. 76 categories of drug formulations considered harmful or lacking adequate therapeutic justification have been prohibited in India .

As per norms prescribed under the Drugs & Cosmetics Rules, 1945, no drug can be manufactured and sold without obtaining a licence from the respective Licensing Authority. For new drug formulations, prior approval of the office of Drugs Controller General (India) is required for grant of manufacturing licence by the State Licensing Authorities.

In so far as the prices of medicines is concerned, this subject falls within the purview of the National Pharmaceutical Pricing Authority(NPPA) which is under the Ministry of Chemicals and Fertilisers. NPPA has informed that they have not conducted any specific study on comparative costs of medicines in India and the West. However, generally drugs are cheaper in India compared to the developed countries and prices compare favourably with the neighbouring countries also.

As per the Drugs Prices Control Order(DPCO), 1995, 74 drugs fall in the price control list. Prices of medicines have by and large remained under control. This is evidenced from the fact that the increase in the wholesale price index for general commodities has consistently been higher than that for drugs in the last four years. The following table illustrates the same. The source of the data is Ministry of Commerce and Industry, Govt. of India.

% Change in Wholesale Price Index (WPI) over preceding year

	2000-01	2001-02	2002-03	2003-04
Drugs and medicines	5.85	3.48	0.71	2.55
All Commodities	7.16	3.60	3.41	5.46

In view of the data given above, it does not seem correct to say that prices of medicines in India have been excessively high. In a dynamic economy, changes in the prices of medicines as of all other commodities would be a normal feature. While the prices of some medicines increase, prices of some decrease.